

EXHIBIT E

1 IN THE UNITED STATE DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4
5 IN RE: ETHICON, INC. PELVIC REPAIR : Master File No.
6 SYSTEM PRODUCTS LIABILITY : 2:12-MD-02327
7 LITIGATION : MDL No. 2327
8 THIS DOCUMENT RELATES TO : JOSEPH R. GOODWIN
9 PLAINTIFFS: : U.S. DISTRICT JUDGE
10 Kathleen Wolfe 2:12-cv-00335 :
11 Cindy Smith 2:12-cv-01149 :
12 Patricia Conti 2:12-cv-00516 :
13 Marty Babcock 2:12-cv-01052 :
14 Patti Ann Phelps 2:12-cv-01171 :
15 Karyn Drake 2:12-cv-00747 :

16

17 DEPOSITION OF NICOLETTE HORBACH, M.D.

18 Washington, D.C.

19 March 25, 2016

20 10:30 a.m.

21

22

23

24 Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

Page 2	Page 4
<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5 The following is the transcript of the</p> <p>6 deposition of NICOLETTE HORBACH, M.D. held at the</p> <p>7 offices of:</p> <p>8</p> <p>9</p> <p>10 O'Melveny & Myers LLP</p> <p>11 1625 Eye Street, NW</p> <p>12 Washington, DC 20006</p> <p>13</p> <p>14</p> <p>15</p> <p>16 Taken pursuant to applicable Rules of Civil</p> <p>17 Procedure, before Linda S. Kinkade, Registered</p> <p>18 Diplomate Reporter, Certified Realtime Reporter,</p> <p>19 Registered Professional Reporter, Registered Merit</p> <p>20 Reporter, Certified Shorthand Reporter, as licensed</p> <p>21 by the State of California, and Notary Public, as</p> <p>22 commissioned by the District of Columbia.</p> <p>23</p> <p>24</p>	<p>1 INDEX OF EXAMINATION</p> <p>2</p> <p>3 EXAMINATION of NICOLETTE HORBACH, M.D. PAGE</p> <p>4 BY MR. CARTMELL 8</p> <p>5 BY MS. CRAWFORD 55</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
Page 3	Page 5
<p>1 APPEARANCES:</p> <p>2</p> <p>3 On Behalf of Plaintiffs in the MDL Litigation:</p> <p>4 Wagstaff & Cartmell, LLP</p> <p>5 By: Thomas P. Cartmell, Esquire</p> <p>6 (Telephonic appearance)</p> <p>7 4740 Grand Avenue</p> <p>8 Suite 300</p> <p>9 Kansas City, Kansas 64112</p> <p>10 tcartmell@wcllp.com</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15 On Behalf of Defendant Ethicon and Johnson &</p> <p>16 Johnson:</p> <p>17 Riker Danzig Scherer Hyland Perretti LLP</p> <p>18 By: Kelly Strange Crawford, Esquire</p> <p>19 One Speedwell Avenue</p> <p>20 Morristown, New Jersey 07962</p> <p>21 kcrawford@riker.com</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 E X H I B I T S</p> <p>2</p> <p>3 NO. DESCRIPTION PAGE</p> <p>4 Exhibit 1 Three-ring binder Nicolette S. 7</p> <p>5 Horbach, M.D. Expert Report</p> <p>6 dated 2/25/16 with Cited</p> <p>7 Articles and contents thereof,</p> <p>8 including Horbach TVT General</p> <p>9 Report & Sources with Tabs 1</p> <p>10 through 48</p> <p>11 Exhibit 2 Pages 5-8 of Document 75 filed 7</p> <p>12 03/22/16</p> <p>13 Exhibit 3 Hansen: Long-Term Follow-up of 7</p> <p>14 Treatment for Synthetic Mesh</p> <p>15 Complications</p> <p>16 Exhibit 4 Device Labeling Guidance #G91-1 7</p> <p>17 (blue book memo) (Text only)</p> <p>18 General Program Memorandum</p> <p>19 Exhibit 5 U.S. Food and Drug 7</p> <p>20 Administration: What is a</p> <p>21 Serious Adverse Event?</p> <p>22 Exhibit 6 NIA Adverse Event and Serious 7</p> <p>23 Adverse Event Guidelines</p> <p>24</p>

Nicolette Horbach, M.D.

<p style="text-align: right;">Page 6</p> <p>1 Exhibit 7 Journal of Clinical Research 7</p> <p>2 Best Practices Adverse Event</p> <p>3 Terminology</p> <p>4 Exhibit 8 Gynecare TVT Tension-free 7</p> <p>5 Support for Incontinence</p> <p>6 Exhibit 9 Handwritten document "174 7</p> <p>7 general"</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 8</p> <p>1 Dr. Horbach had coming into this deposition today.</p> <p>2 MR. CARTMELL: Thanks, Kelly, for that.</p> <p>3 I do think that is a fair representation of the</p> <p>4 agreement that was made among the parties. I will</p> <p>5 say this, though. I think it was represented to us</p> <p>6 as plaintiff's counsel in the MDL that the doctor</p> <p>7 does not have any new opinions that have arisen</p> <p>8 related to the TVT Retropubic product that she's</p> <p>9 giving opinions on in this case, and, therefore,</p> <p>10 this was just going to be a general update</p> <p>11 deposition limited, as you said, to one hour. If</p> <p>12 in fact she does have additional opinions, then</p> <p>13 we'll have to revisit that. Fair enough?</p> <p>14 MS. CRAWFORD: Fair.</p> <p>15 EXAMINATION</p> <p>16 BY MR. CARTMELL:</p> <p>17 Q. Good morning, doctor. As I said, my</p> <p>18 name is Tom Cartmell, and I represent the</p> <p>19 plaintiffs in this case. We've never met before;</p> <p>20 is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. And you are in, I understand it, you are</p> <p>23 in Washington, D.C. right now; is that correct?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 7</p> <p>1 PROCEEDINGS</p> <p>2 (Exhibit 1 was marked for identification.)</p> <p>3 (Exhibit 2 was marked for identification.)</p> <p>4 (Exhibit 3 was marked for identification.)</p> <p>5 (Exhibit 4 was marked for identification.)</p> <p>6 (Exhibit 5 was marked for identification.)</p> <p>7 (Exhibit 6 was marked for identification.)</p> <p>8 (Exhibit 7 was marked for identification.)</p> <p>9 (Exhibit 8 was marked for identification.)</p> <p>10 (Exhibit 9 was marked for identification.)</p> <p>11</p> <p>12 NICOLETTE HORBACH, M.D.,</p> <p>13 Having been first duly sworn, was thereafter</p> <p>14 examined and testified as follows:</p> <p>15 MS. CRAWFORD: Kelly Crawford on behalf</p> <p>16 of Ethicon and Johnson & Johnson.</p> <p>17 MR. CARTMELL: This is Tom Cartmell on</p> <p>18 behalf of the plaintiffs in the MDL litigation.</p> <p>19 MS. CRAWFORD: And I'll just make a</p> <p>20 statement for the record, Mr. Cartmell. My</p> <p>21 understanding is this deposition of Dr. Horbach is</p> <p>22 intended to be limited to an hour based upon</p> <p>23 updated information in her general TVT report, and</p> <p>24 that is the presumption that Ethicon and</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. I'm actually doing this deposition by</p> <p>2 phone, which I know is not ideal, so I would just</p> <p>3 ask that, if you can't understand me for any reason</p> <p>4 or just don't understand a question, or can't hear</p> <p>5 me, just ask me to rephrase it and I'll do that.</p> <p>6 Okay?</p> <p>7 A. That's fine, yes.</p> <p>8 Q. You understand that you have been</p> <p>9 identified as a general causation expert related to</p> <p>10 the TVT Retropubic product in Wave 1 of the Ethicon</p> <p>11 MDL? Do you understand that?</p> <p>12 A. Yes, I think I understand Wave 1 is this</p> <p>13 group of patients that are being presented, yes.</p> <p>14 Q. Okay. And do you understand that you</p> <p>15 have been identified to give general opinions</p> <p>16 related to the TVT Retropubic product manufactured</p> <p>17 by Ethicon?</p> <p>18 A. Yes.</p> <p>19 Q. Now when I refer to TVT Retropubic, do</p> <p>20 you understand that I am referring to the product</p> <p>21 that was manufactured and initially brought to</p> <p>22 market by Ethicon, I believe in January of 1998, in</p> <p>23 the United States?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 10</p> <p>1 Q. And you understand, I take it, from your</p> <p>2 prior depositions that there's actually two</p> <p>3 versions of the TVT Retropubic product that</p> <p>4 continue to be sold, one in the laser-cut mesh or</p> <p>5 with the laser-cut mesh, and one with the</p> <p>6 mechanical-cut mesh; is that correct?</p> <p>7 A. Yes.</p> <p>8 Q. Are your opinions in this case, meaning</p> <p>9 the Wave 1 litigation that you've been identified</p> <p>10 in, going to be related to both the mechanical-cut</p> <p>11 versions of the TVT Retropubic product and the</p> <p>12 laser-cut versions?</p> <p>13 A. Yes.</p> <p>14 Q. And I take it that all of your opinions</p> <p>15 related to the safety and efficacy of those</p> <p>16 products, including the laser-cut version and the</p> <p>17 mechanical-cut version, are contained in your</p> <p>18 report that you have produced in this litigation;</p> <p>19 is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Now I want to, if we can, go through</p> <p>22 quickly the materials you brought with you today,</p> <p>23 but actually, before I do that, let me go back to</p> <p>24 your identification in this wave of Ethicon cases</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. Did you bring that with you today?</p> <p>2 A. No.</p> <p>3 Q. Okay. Why is that?</p> <p>4 MS. CRAWFORD: We were instructed that</p> <p>5 this was general only and not case specific.</p> <p>6 MR. CARTMELL: Okay.</p> <p>7 THE WITNESS: Correct, that's what I was</p> <p>8 told.</p> <p>9 BY MR. CARTMELL:</p> <p>10 Q. Doctor, that Drake case that you've been</p> <p>11 identified in, do you know whether the TVT</p> <p>12 Retropubic product that was implanted in Ms. Drake</p> <p>13 was a laser-cut product or a mechanical-cut</p> <p>14 product?</p> <p>15 MS. CRAWFORD: I'm going to object just</p> <p>16 because I don't know that the doctor is prepared to</p> <p>17 respond to questions about Drake because it wasn't</p> <p>18 contemplated it would be covered at this deposition</p> <p>19 today, but if she's able to answer it and you want</p> <p>20 to ask that during your hour, I'm going to let her</p> <p>21 answer the question.</p> <p>22 THE WITNESS: Okay. I can't answer that</p> <p>23 for you at this point. I didn't prepare for that</p> <p>24 part.</p>
<p style="text-align: right;">Page 11</p> <p>1 called Wave 1 by the parties and the court.</p> <p>2 You've also been identified to give</p> <p>3 case-specific opinions in one case; is that right?</p> <p>4 A. Yes. Drake.</p> <p>5 Q. The plaintiff's name or the patient's</p> <p>6 name in that case is Ms. Drake; is that right?</p> <p>7 A. Yes, that's correct.</p> <p>8 Q. And is that the only case that you have</p> <p>9 been identified to give case-specific opinions in?</p> <p>10 MS. CRAWFORD: For Wave 1?</p> <p>11 MR. CARTMELL: Yes. Sorry.</p> <p>12 THE WITNESS: I believe so. I've been</p> <p>13 asked to give opinions for another patient, but I</p> <p>14 don't think she's in Wave 1.</p> <p>15 BY MR. CARTMELL:</p> <p>16 Q. Okay. I'll get to that in a minute.</p> <p>17 With respect to the Drake case that you are</p> <p>18 identified as an expert, case-specific expert in, I</p> <p>19 take it you've reviewed Ms. Drake's medical</p> <p>20 records; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. And you produced a report related to</p> <p>23 that?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 13</p> <p>1 BY MR. CARTMELL:</p> <p>2 Q. Okay. And let me just ask, have you</p> <p>3 ever looked to determine that? In other words, you</p> <p>4 knew at one time; you're just not prepared to</p> <p>5 answer that today.</p> <p>6 MS. CRAWFORD: Objection. You can</p> <p>7 answer.</p> <p>8 THE WITNESS: Yeah, I'm pretty sure that</p> <p>9 I had seen the information. I just don't remember</p> <p>10 since the cases tend to merge together.</p> <p>11 BY MR. CARTMELL:</p> <p>12 Q. Okay. All right. Now let's go through</p> <p>13 real quickly, if we can, the items that you brought</p> <p>14 with you, and before we got on the record counsel</p> <p>15 on behalf of Ethicon, I think, has marked as an</p> <p>16 exhibit everything that you brought with you. Is</p> <p>17 that your understanding?</p> <p>18 A. Yes, that's correct.</p> <p>19 Q. My memory is that Exhibit 1 is a binder</p> <p>20 that you brought with several subparts. Would you</p> <p>21 just real quickly tell us what is contained in that</p> <p>22 binder?</p> <p>23 A. The Exhibit 1 binder contains a copy of</p> <p>24 my general report from February 25th, 2016, a</p>

<p style="text-align: right;">Page 14</p> <p>1 section involved with the reliance list, which is 2 the information that has been forwarded to me over 3 time by Ethicon, and the third section are the 4 specific articles that are cited in my general 5 report from the February 25th, 2016. 6 Q. Thank you. Let me ask a few follow-up 7 questions. The reliance list that you referred to, 8 was that prepared by you or counsel for Ethicon? 9 A. That was prepared by Ethicon. 10 Q. Okay. And does that contain all of the 11 articles or documents that you have reviewed and 12 rely on in forming your opinions in this case? 13 A. It -- I have not looked at the current 14 reliance list in this particular binder, as I just 15 received the binder last night via Federal Express. 16 These are definitely things that Ethicon has sent 17 me. I have previously in my last deposition 18 brought additional reference list of articles that 19 I had looked at in referring to my -- or in 20 formulating my general report. I don't know 21 whether or not those are specifically included. So 22 there may be additional articles that are not in 23 this reliance list that I myself have pulled and 24 I've used in my opinion.</p>	<p style="text-align: right;">Page 16</p> <p>1 spend my hour looking through these many pages to 2 determine if those additional references that I've 3 used are in the reliance list. Part of the 4 difficult -- 5 Q. Is your -- 6 A. Go ahead. 7 Q. Go ahead. 8 A. No, I'm fine. Thank you. 9 Q. Now I've looked at that reliance list, 10 and there are hundreds of articles, if not a 11 thousand, and thousands and thousands of pages of 12 documents. Fair to say that, to review all of that 13 information on your reliance list, would take you 14 hundreds and hundreds of hours to review if you 15 reviewed all those pages? 16 MS. CRAWFORD: Objection. You can 17 answer. 18 THE WITNESS: I can't tell you how many 19 hours it would take me, but I know I've definitely 20 worked hundreds of hours on this particular issue. 21 BY MR. CARTMELL: 22 Q. Okay. And so without going through each 23 and every item on that reliance list, it would be 24 hard for you to say today which of those you have</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Okay. Thank you for that. Have you 2 actually looked at all of the documents that are 3 identified on your reliance list that is in the 4 binder marked Exhibit 1? 5 A. I've looked at the bulk of them. I 6 don't know whether I could tell you that I've read 7 every single one of them because sometimes I may 8 not have felt that they were applicable to what I 9 was looking for for my opinion. And, in addition, 10 there are information in here that's actually part 11 of Prolift documents that were sent to me in my 12 review of Prolift. 13 Q. Okay. So is it fair to say that there 14 may be some information on that reliance list that, 15 for one reason or another, you have not actually 16 reviewed and are not actually relying on in forming 17 your opinions in this case? 18 A. Correct. 19 Q. And now -- 20 A. Sorry. 21 Q. I'm sorry. Go ahead. 22 A. I'm just saying, and there may -- and 23 there may be other documents that aren't included 24 specifically in the reliance list, again, unless I</p>	<p style="text-align: right;">Page 17</p> <p>1 reviewed or which you haven't reviewed, correct? 2 A. Without going through each individual 3 one, no. 4 Q. And I take it there is information on 5 that reliance list that, rather than look at the 6 information in detail, you have skimmed, for 7 example, the information; is that fair? 8 A. There may be, yes, part of what's listed 9 here I may have skimmed rather than read word for 10 word. 11 Q. I see. Now all of the documents on 12 there that are internal corporate documents 13 produced confidentially in this litigation, were 14 those all provided to you by defense counsel? 15 A. If it's listed in the reliance list, it 16 is my assumption that they were all sent to me. 17 Q. Were there any internal corporate 18 documents from Ethicon or Johnson & Johnson that 19 you specifically requested to see related to the 20 TVT Retropubic product? 21 A. Probably I have, although I can't 22 specifically tell you which since I started 23 reviewing this back in 2012 or '13, so it's been 24 quite some time.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. I don't have your reliance list</p> <p>2 obviously that is in Exhibit 1. When did you say</p> <p>3 that that was provided to you?</p> <p>4 A. I received it yesterday by Federal</p> <p>5 Express.</p> <p>6 MS. CRAWFORD: Tom, it's Kelly. I</p> <p>7 apologize if this isn't the case, but normally that</p> <p>8 reliance list is the Exhibit B to the expert</p> <p>9 report. It's normally produced with it. If that</p> <p>10 didn't happen in this case, we can certainly follow</p> <p>11 up on that, but I would have assumed that that</p> <p>12 happened.</p> <p>13 MR. CARTMELL: I appreciate that, Kelly.</p> <p>14 I'm not certain whether or not it was or wasn't. I</p> <p>15 just don't know if that one in the exhibit is any</p> <p>16 different than the reliance list that we have, and</p> <p>17 we do have one.</p> <p>18 MS. CRAWFORD: Okay.</p> <p>19 MR. CARTMELL: So I don't know if there's</p> <p>20 been any updates since the one that was provided to</p> <p>21 us. Do you know that, Kelly?</p> <p>22 MS. CRAWFORD: I don't know the answer to</p> <p>23 that and I'll find out for you.</p> <p>24 MR. CARTMELL: Okay. Thank you.</p>	<p style="text-align: right;">Page 20</p> <p>1 your deposition in December of 2015 in the Corbet</p> <p>2 case, at that time your testimony was you had not</p> <p>3 reviewed any Ethicon employees' or corporate</p> <p>4 representatives' depositions as of that time. Do</p> <p>5 you recall that?</p> <p>6 A. I don't recall stating that. I mean,</p> <p>7 I've certainly in the past have looked at, I think,</p> <p>8 David Robinson and one or two of the other</p> <p>9 corporate depositions. I think that was more</p> <p>10 related to the Prolift cases.</p> <p>11 And so if I answered it specifically for no</p> <p>12 for the TVT cases, it may have just been because of</p> <p>13 separating it out from my perspective rather than</p> <p>14 putting it all together as one.</p> <p>15 Q. Okay. So is your testimony that, if you</p> <p>16 testified in the Corbet case that you had not</p> <p>17 reviewed any corporate witness testimony as of that</p> <p>18 time, that in fact your testimony at that time was</p> <p>19 not correct?</p> <p>20 A. That is not what I'm saying. I'm saying</p> <p>21 if I -- if I answered in my deposition in December</p> <p>22 that I had not reviewed any corporate employee</p> <p>23 depositions, that that was specifically answering</p> <p>24 relative to my preparation of my TVT general</p>
<p style="text-align: right;">Page 19</p> <p>1 BY MR. CARTMELL:</p> <p>2 Q. Doctor, are there any depositions</p> <p>3 included on that reliance list?</p> <p>4 A. Just a minute. I'll have to look</p> <p>5 through.</p> <p>6 Q. You know what, doctor? Let me try to</p> <p>7 save some time.</p> <p>8 A. Okay. I'm just sort of going through,</p> <p>9 because, as I said, there's a fair number of things</p> <p>10 here. I don't see -- I don't see right now</p> <p>11 depositions on this, although I know I have</p> <p>12 depositions that I have reviewed.</p> <p>13 Q. Okay. And I want to ask you about that</p> <p>14 right now. I've read your prior testimony in the</p> <p>15 Corbet case and then in the Wicker case.</p> <p>16 First of all, what depositions of Ethicon</p> <p>17 employees have you reviewed?</p> <p>18 A. Unfortunately, because this was not part</p> <p>19 of what was -- I was told was going to be covered.</p> <p>20 I haven't prepared and looked back at all of that</p> <p>21 in what I've reviewed from the last three or four</p> <p>22 years to be able to tell you which depositions I've</p> <p>23 read.</p> <p>24 Q. Okay. Well, my understanding is from</p>	<p style="text-align: right;">Page 21</p> <p>1 report. It did not necessarily reflect that I have</p> <p>2 never read them as part of my evaluation of the</p> <p>3 Prolift.</p> <p>4 Q. Okay. So let's clarify that. Is it</p> <p>5 still the case today that you have not reviewed any</p> <p>6 corporate Ethicon employees' depositions in</p> <p>7 preparation for your opinions related to the TVT</p> <p>8 product?</p> <p>9 A. I think that is accurate, yes.</p> <p>10 Q. Okay. And you had, I take it from your</p> <p>11 prior answer, reviewed corporate representatives'</p> <p>12 testimony related to the Prolift product; is that</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. And you mentioned David Robinson's</p> <p>16 deposition. Have you reviewed any other corporate</p> <p>17 representatives' or employees' depositions related</p> <p>18 to the Prolift product?</p> <p>19 A. Yes.</p> <p>20 Q. Who else?</p> <p>21 A. I can't possibly tell you. That was a</p> <p>22 while back and I'm very bad with names.</p> <p>23 Q. Can you name any additional witnesses</p> <p>24 whose depositions you may have read related to the</p>

<p style="text-align: right;">Page 22</p> <p>1 Prolift product?</p> <p>2 A. I said, no, I can't. Unfortunately, as</p> <p>3 I said, I'm very bad with names, so I can't -- his</p> <p>4 name I recall, but I don't recall the other names.</p> <p>5 Q. Okay. All right. So let's continue</p> <p>6 naming or identifying what you have marked. My</p> <p>7 understanding is that Exhibit 2 is the notice or</p> <p>8 portions of the notice for deposition today; is</p> <p>9 that correct?</p> <p>10 A. Yes.</p> <p>11 Q. Why don't you, if you wouldn't mind,</p> <p>12 going through Exhibits 3 through 9 -- I believe 9</p> <p>13 is the last exhibit that you identified -- go ahead</p> <p>14 and tell us briefly on the record what each of</p> <p>15 those exhibits is, please.</p> <p>16 A. Exhibit 3 is an article by Hansen</p> <p>17 entitled Long-Term Follow-Up of Treatment for</p> <p>18 Synthetic Mesh Complications, and, in addition,</p> <p>19 there are the abstracts of several articles</p> <p>20 referenced in the Hansen article that are attached</p> <p>21 to that exhibit.</p> <p>22 Q. Okay. And is that an article that you</p> <p>23 brought specifically with you to the deposition</p> <p>24 today?</p>	<p style="text-align: right;">Page 24</p> <p>1 ever reviewed any FDA guidelines or guidance</p> <p>2 documents related to labeling of medical devices?</p> <p>3 A. Not that I can recall.</p> <p>4 Q. Okay. Go ahead and continue, please.</p> <p>5 A. The Exhibit 5 is listed as the FDA "What</p> <p>6 is a serious adverse event?" definitions.</p> <p>7 Q. Again, the same question. Is that</p> <p>8 something you just received recently?</p> <p>9 A. No, I pulled that myself.</p> <p>10 Q. When did you pull that?</p> <p>11 A. Recently in preparation for the</p> <p>12 deposition.</p> <p>13 Q. Okay. So, for example, as of the time</p> <p>14 of writing your report, that's not something that</p> <p>15 you had reviewed or relied on in developing your</p> <p>16 opinions, fair?</p> <p>17 A. No. I mean, that's part of -- it is</p> <p>18 confirmatory information for what I was already</p> <p>19 aware of, but it's just specifically laid out in</p> <p>20 detail, and I had reviewed previously information</p> <p>21 on serious adverse events and different criteria</p> <p>22 that have been used for defining serious adverse</p> <p>23 events in preparation for my prior general report.</p> <p>24 Q. I understand, but as far as the contents</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Yes.</p> <p>2 Q. Why is that? That's a poor question.</p> <p>3 Sorry.</p> <p>4 Why is it that you specifically brought that</p> <p>5 article? Is it something you recently received or</p> <p>6 why did you bring that?</p> <p>7 A. Because I was asked to bring all of the</p> <p>8 documents in my possession that I have relative to</p> <p>9 this issue and that's a more recent -- I pulled</p> <p>10 those articles or those abstracts more recently.</p> <p>11 Q. All right. Go ahead and continue,</p> <p>12 please.</p> <p>13 A. The next is Exhibit 4 that is listed as</p> <p>14 a General Program Memorandum from 1991 from the FDA</p> <p>15 regarding device labeling guidance.</p> <p>16 Q. Was that provided to you or is that</p> <p>17 something you looked for?</p> <p>18 A. Part of this was provided to me and part</p> <p>19 of it I looked for.</p> <p>20 Q. Okay. And when was the first time you</p> <p>21 saw that document?</p> <p>22 A. Fairly recently, in the last week or</p> <p>23 two.</p> <p>24 Q. Before reviewing that document, had you</p>	<p style="text-align: right;">Page 25</p> <p>1 of that document, that is, Exhibit 5, is that</p> <p>2 information that you had reviewed, that specific</p> <p>3 information included in that document, prior to</p> <p>4 writing your report in this case?</p> <p>5 A. This particular document I had not seen</p> <p>6 prior to my report, but the information within the</p> <p>7 document I was aware of prior to my report.</p> <p>8 Q. Okay. Go ahead and continue, please.</p> <p>9 A. The next is from the NIH, The National</p> <p>10 Institutes, on aging, and it's their guidelines</p> <p>11 regarding adverse events and the definition of</p> <p>12 serious adverse events guidelines.</p> <p>13 Q. When was the first time you reviewed</p> <p>14 that document?</p> <p>15 A. This particular one that I pulled,</p> <p>16 again, I reviewed it fairly recently. I have seen</p> <p>17 similar documentation previously.</p> <p>18 Q. Okay. And that's on your reliance list,</p> <p>19 the similar documentation?</p> <p>20 A. I would have to look through to make</p> <p>21 sure that it is.</p> <p>22 Q. Just so it's clear for the testimony, is</p> <p>23 it your testimony under oath that the information</p> <p>24 contained in that exhibit you had actually seen</p>

<p style="text-align: right;">Page 26</p> <p>1 prior to writing your report?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. Continue, please.</p> <p>4 A. Exhibit 7 is an article from what's</p> <p>5 called the Journal of Clinical Research Best</p> <p>6 Practices, and it is entitled -- it is an article</p> <p>7 entitled Adverse Event Terminology, and it lists</p> <p>8 different adverse event definitions that are used</p> <p>9 by different organizations, including the U.S. Drug</p> <p>10 Regulations, the National Cancer Institute, Medical</p> <p>11 Device Regulations Guidance and ISO Guidelines,</p> <p>12 European Directive and Guidelines.</p> <p>13 Q. Okay. When is the first time you</p> <p>14 received and reviewed that document?</p> <p>15 A. I pulled this document myself as an</p> <p>16 example of the different variations on what is used</p> <p>17 to define an adverse event, and I pulled that in</p> <p>18 preparation for this deposition.</p> <p>19 Q. Had you seen that prior to the time of</p> <p>20 writing your report?</p> <p>21 A. This specific document itself, no; parts</p> <p>22 of the document, yes.</p> <p>23 Q. Okay. What else? You can continue,</p> <p>24 please.</p>	<p style="text-align: right;">Page 28</p> <p>1 the current general report from February is</p> <p>2 essentially a combination of those two reports with</p> <p>3 a couple additional statements in it.</p> <p>4 Q. So is it fair to say that you first saw</p> <p>5 the revised or new IFU from 2015 for the TVT</p> <p>6 Retropubic product in or around November of 2015;</p> <p>7 is that fair?</p> <p>8 A. No, I said prior to -- in preparing that</p> <p>9 report, and I can't say whether it was in February</p> <p>10 of 2015 or in October of 2015.</p> <p>11 Q. Can you ballpark it?</p> <p>12 A. No.</p> <p>13 Q. Okay. And with respect -- okay. Why</p> <p>14 don't you go ahead and continue with Exhibit 9,</p> <p>15 please.</p> <p>16 A. And the last, Exhibit 9, is a</p> <p>17 handwritten statement by me saying "174 general."</p> <p>18 Q. When did you write that piece of paper</p> <p>19 marked as Exhibit 9?</p> <p>20 A. This morning.</p> <p>21 Q. And what does that reflect or refer to?</p> <p>22 A. I was asked to produce information</p> <p>23 regarding the number of hours that I had spent in</p> <p>24 preparation of review of the literature and</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Exhibit 8 is the TVT instructions for</p> <p>2 use that is the most recent -- the most recent</p> <p>3 version.</p> <p>4 Q. I think that you're referring to the</p> <p>5 2015 IFU that was released that has additional</p> <p>6 warnings and adverse reactions in it; is that</p> <p>7 right?</p> <p>8 A. It's the one that was released in</p> <p>9 January 2015.</p> <p>10 Q. When is the first time that you had seen</p> <p>11 that new IFU that was actually released related to</p> <p>12 the TVT Retropubic product in 2015?</p> <p>13 A. During the formulation of my</p> <p>14 supplemental report.</p> <p>15 Q. Supplemental report in this case?</p> <p>16 A. Yes, the supplemental report was back</p> <p>17 in, I think, November or so of 2015 when I wrote</p> <p>18 that.</p> <p>19 Q. Are you talking about your report, your</p> <p>20 supplemental report, in the Corbet case?</p> <p>21 A. I'm not sure how you term it, but there</p> <p>22 was the original general report from July of 2014,</p> <p>23 there was a supplemental general report submitted</p> <p>24 in either November or December of 2015, and then</p>	<p style="text-align: right;">Page 29</p> <p>1 preparation of my -- my general reports in the TVT</p> <p>2 situation, and that represents my best ability to</p> <p>3 put that together.</p> <p>4 Q. Okay. Let me follow up on that a bit.</p> <p>5 Now, I know that you testified in the past</p> <p>6 that you first became a consultant in litigation for</p> <p>7 Ethicon in, I believe, 2012; is that fair?</p> <p>8 A. I think it was around 2012, yes.</p> <p>9 Q. Okay. And since that time my</p> <p>10 understanding is that you have given depositions in</p> <p>11 a case called Corbet and a case called Wicker, and</p> <p>12 I believe there might be one more prior to today;</p> <p>13 is that correct?</p> <p>14 A. That's correct. There are three -- I'm</p> <p>15 sorry. I've given three depositions that I recall.</p> <p>16 Q. Do you remember the case name in the</p> <p>17 other deposition, the third that I did not mention?</p> <p>18 A. It was -- I was deposed as just a</p> <p>19 general expert. That was the deposition in</p> <p>20 December -- on December 23rd, 2015.</p> <p>21 Q. Okay. I think that was the Corbet</p> <p>22 deposition, but --</p> <p>23 MR. CARTMELL: Do you know, Kelly, was</p> <p>24 it --</p>

<p style="text-align: right;">Page 30</p> <p>1 MS. CRAWFORD: No, she was deposed in --</p> <p>2 prior to the Corbet trial sitting as a general</p> <p>3 expert.</p> <p>4 THE WITNESS: I've not been deposed on</p> <p>5 Corbet as a -- as the case-specific expert. I</p> <p>6 think the other deposition was actually Schubert,</p> <p>7 you're correct, as a Prolift. So Wicker and</p> <p>8 Schubert for Prolift, and then TVT deposition as a</p> <p>9 general expert, not as a case-specific expert.</p> <p>10 BY MR. CARTMELL:</p> <p>11 Q. Okay. I appreciate you clarifying that.</p> <p>12 Okay.</p> <p>13 So this number of 174 that you've listed this</p> <p>14 morning on Exhibit 9, is that the number of hours</p> <p>15 that you have actually spent in preparing your</p> <p>16 opinions prior to today related to the Wave 1 cases</p> <p>17 only?</p> <p>18 A. Again, the Wave 1 issue is something I'm</p> <p>19 not quite as familiar with. It is the number of</p> <p>20 hours I've spent to prepare the general reports,</p> <p>21 the different versions of general reports, that you</p> <p>22 all have on specifically just the midurethral</p> <p>23 slings.</p> <p>24 Q. I see. And those reports are just</p>	<p style="text-align: right;">Page 32</p> <p>1 about your -- related to your TVT-R opinions in</p> <p>2 this case and in the cases that you testified about</p> <p>3 TVT-R. How much of that time has involved actual</p> <p>4 review of the documents on your reliance list, your</p> <p>5 best guess?</p> <p>6 A. I would say -- as I said, I can't really</p> <p>7 tell you because it's been a combination of</p> <p>8 reviewing the articles on the reliance list, doing</p> <p>9 my own research in the library and pulling my own</p> <p>10 articles that I wanted to review, and the writing</p> <p>11 part. So it's hard for me to really give you</p> <p>12 specifics about how many hours I did what.</p> <p>13 Q. Well, give me your best guess on</p> <p>14 reviewing materials.</p> <p>15 A. I can't -- I mean, it would still -- I</p> <p>16 just can't give you an accurate guess.</p> <p>17 Q. You can't give me any sort of</p> <p>18 guesstimate of how much time you've spent reviewing</p> <p>19 materials related to your opinions; is that fair?</p> <p>20 A. I mean, essentially the time has been</p> <p>21 either meeting, review of materials or writing,</p> <p>22 so ...</p> <p>23 Q. And what I'm trying to do is get your</p> <p>24 best estimate of how much time that is reviewing</p>
<p style="text-align: right;">Page 31</p> <p>1 referring to the TVT Retropubic, correct?</p> <p>2 A. It refers to the TVT Retropubic, and I</p> <p>3 think there's -- it also refers to the TVT Exact.</p> <p>4 Q. Okay. And so would it be fair for me to</p> <p>5 say that, prior to today, you have spent 174 hours</p> <p>6 in developing your TVT Retropubic opinions</p> <p>7 regardless of whether that includes time meeting</p> <p>8 with counsel for Ethicon or doing research or</p> <p>9 writing your report?</p> <p>10 A. Yes, for just -- this does not include</p> <p>11 any review of patient-specific medical records or</p> <p>12 depositions.</p> <p>13 Q. Okay. Now of that 174 hours I want you</p> <p>14 to try to guesstimate for me. How much of that</p> <p>15 time has been spent meeting with or talking with</p> <p>16 counsel for defense about TVT Retropubic or Exact?</p> <p>17 A. Maybe 20 or so. It's hard, I mean, it's</p> <p>18 hard for me to say over a couple of year time</p> <p>19 period. It could be a little bit more, but not a</p> <p>20 substantial number of hours.</p> <p>21 Q. Okay. The 20 is your best guess.</p> <p>22 That's fair enough, right?</p> <p>23 A. Yeah, 20 or 30 at the most, but, yeah.</p> <p>24 Q. Okay. And then we're still talking</p>	<p style="text-align: right;">Page 33</p> <p>1 materials. You've already told me about your best</p> <p>2 guess meeting with counsel.</p> <p>3 A. It's probably been maybe 100 plus hours.</p> <p>4 I don't know.</p> <p>5 Q. Okay. Now all of that 174 hours, has</p> <p>6 that been at \$500 an hour?</p> <p>7 A. Yes.</p> <p>8 Q. And how much of that 174 hours has been</p> <p>9 since you actually submitted your report in this</p> <p>10 case?</p> <p>11 A. I've received zero to date.</p> <p>12 MS. CRAWFORD: I don't think that was the</p> <p>13 question.</p> <p>14 THE WITNESS: Is that what you're asking?</p> <p>15 BY MR. CARTMELL:</p> <p>16 Q. No, no. Let me restate it. How many of</p> <p>17 the 174 hours has been spent by you since you</p> <p>18 actually submitted your Wave 1 report in this case</p> <p>19 on TVT Retropubic?</p> <p>20 A. Can you specify what report is</p> <p>21 considered to be the Wave 1 report?</p> <p>22 Q. Well, it's your report. You signed it</p> <p>23 and submitted it in this case.</p> <p>24 A. I have -- I have three different dates</p>

<p style="text-align: right;">Page 34</p> <p>1 that I have submitted reports, so I'm asking you --</p> <p>2 Q. Well, let me try and clarify. I don't</p> <p>3 mean to interrupt you, but the one that you brought</p> <p>4 with you today that is marked in Exhibit 1, that</p> <p>5 report is the one I'm talking about.</p> <p>6 A. Okay. Then I think --</p> <p>7 Q. How much of the time has been since</p> <p>8 then?</p> <p>9 A. Probably six or seven hours.</p> <p>10 Q. Okay. And that includes meeting with</p> <p>11 defense counsel and preparing on your own for this</p> <p>12 deposition, I take it.</p> <p>13 A. Correct.</p> <p>14 Q. Okay. Now I want to try to get an</p> <p>15 understanding of how many hours you have spent</p> <p>16 related to your opinions that you've given in mesh</p> <p>17 litigation on the Prolift product. Can you</p> <p>18 ballpark or give me your best estimate on how many</p> <p>19 hours you have spent related to your Prolift</p> <p>20 opinions?</p> <p>21 MS. CRAWFORD: Tom, I'm going to object.</p> <p>22 I specifically didn't ask the doctor to calculate</p> <p>23 that for us today, and I think it would be very</p> <p>24 hard for her to do it and it's not part of the</p>	<p style="text-align: right;">Page 36</p> <p>1 THE WITNESS: The only answer I can give</p> <p>2 you is it's been more hours than what I've done for</p> <p>3 the TVT.</p> <p>4 BY MR. CARTMELL:</p> <p>5 Q. So greater than 174 hours; is that fair?</p> <p>6 A. Correct.</p> <p>7 Q. And is that information that you would</p> <p>8 have available to you? In other words, I take it</p> <p>9 you could find out those -- or that number of</p> <p>10 hours; is that fair?</p> <p>11 A. Correct.</p> <p>12 Q. Okay.</p> <p>13 MR. CARTMELL: And, Kelly, I would just</p> <p>14 ask that you -- and I'll submit something -- that</p> <p>15 you provide us that, and again, if there's an</p> <p>16 objection, we can take it up, but I would like -- I</p> <p>17 think it's discoverable. I think the dispute is</p> <p>18 whether or not at a specific trial if it comes in,</p> <p>19 but I'd ask that you provide me those hours related</p> <p>20 to all of her Prolift work as well. Okay?</p> <p>21 THE WITNESS: Does that include case</p> <p>22 specific or just general?</p> <p>23 MS. CRAWFORD: Why don't you send a</p> <p>24 written request, Tom, and we'll respond to it. I'm</p>
<p style="text-align: right;">Page 35</p> <p>1 scope of today. We can certainly get that</p> <p>2 information to you at a later time. I mean, I'm</p> <p>3 not going to direct her not to answer the question,</p> <p>4 but I don't think she's prepared to answer that</p> <p>5 today.</p> <p>6 MR. CARTMELL: Okay. Well, I just need</p> <p>7 an answer from her. I guess if your position is</p> <p>8 that, you know, in this general deposition I'm not</p> <p>9 entitled to get, you know, the number of hours she</p> <p>10 spent on mesh litigation, I disagree with that. I</p> <p>11 think you're saying you'll give it to me, but I</p> <p>12 want to know if she has any idea today how many</p> <p>13 hours she has spent in mesh litigation as a</p> <p>14 consultant for Ethicon related to the Prolift or</p> <p>15 other products.</p> <p>16 MS. CRAWFORD: Okay. So just for the</p> <p>17 record I am placing an objection. I understand at</p> <p>18 the national level there's a dispute and a debate</p> <p>19 between the parties as to either party's right to</p> <p>20 the answer to that question that is being resolved</p> <p>21 at a pay grade above mine, and I will allow her to</p> <p>22 answer the question, if she can today, but I do</p> <p>23 believe it's beyond the scope of this deposition</p> <p>24 today.</p>	<p style="text-align: right;">Page 37</p> <p>1 sure you'll get it. If you send me the specific</p> <p>2 request, we'll respond to it.</p> <p>3 MR. CARTMELL: Okay.</p> <p>4 BY MR. CARTMELL:</p> <p>5 Q. Doctor, you just raised a point that I</p> <p>6 want to follow up on. How many case-specific hours</p> <p>7 have you spent reviewing medical records, forming</p> <p>8 opinions in TVT cases?</p> <p>9 MS. CRAWFORD: Objection for the record.</p> <p>10 THE WITNESS: I don't have that specific</p> <p>11 number with me today since this was supposed to be</p> <p>12 general report. However, I've reviewed two</p> <p>13 case-specific records for TVTs, the Drake case --</p> <p>14 MS. CRAWFORD: Before you respond, Tom,</p> <p>15 I'm sorry, I have to interrupt her because I don't</p> <p>16 know the answer to whether or not what she's about</p> <p>17 to tell you is something that she has yet been</p> <p>18 designated or not. And if she hasn't been, I would</p> <p>19 object to the name of that at this point in time as</p> <p>20 work product, and I would direct her not to answer</p> <p>21 that question.</p> <p>22 MR. CARTMELL: That's fair enough. We</p> <p>23 can take it up, if we need to.</p> <p>24 BY MR. CARTMELL:</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. Let me follow up without the name. 2 There are two case-specific TVT cases that you have 3 been involved with and spent time on reviewing; is 4 that fair? 5 A. Yes. 6 Q. Okay. And can you ballpark for me the 7 amount of time you spent in those two cases related 8 to, you know, your opinions, whether it be 9 reviewing those records or actually drafting 10 reports? 11 MS. CRAWFORD: Objection. You can 12 answer. 13 THE WITNESS: Probably 75 to a hundred. 14 I think that's probably the best range that I can 15 give you. It could be a little more; it could be a 16 little bit less. 17 BY MR. CARTMELL: 18 Q. Okay. And, again, that's information 19 that you have available to you and could find, 20 fair? 21 A. Yes. 22 Q. Okay. So but I think what you're saying 23 is that we could add 75 to a hundred 24 approximately -- and I'm not holding you</p>	<p style="text-align: right;">Page 40</p> <p>1 THE WITNESS: No, I don't believe I've -- 2 no, I haven't reviewed or been asked to consult on 3 any other products. 4 BY MR. CARTMELL: 5 Q. Okay. I appreciate that. Okay. 6 Are there any other documents that we 7 haven't already discussed that you brought with you 8 today? 9 A. I don't believe so. 10 Q. Now you testified in the Corbet case -- 11 well, let me ask you. How is it that you keep 12 track of these hours? Do you have an electronic 13 document that could be produced that has the hours 14 you've spent or how is it that you keep track of 15 your hours in the mesh litigation as a whole? 16 A. I am sort of an old-fashioned person, so 17 I have a paper calendar, and on my paper calendar I 18 indicate hours I've spent on a particular day in 19 review of the -- in working as an expert in these 20 cases. 21 Q. And I take it you have maintained those 22 back to 2012? 23 A. Yes. 24 Q. Okay. And I noticed in Corbet, as of</p>
<p style="text-align: right;">Page 39</p> <p>1 specifically to the number -- but we could add 75 2 to a hundred to the 174, and that would make up all 3 of the TVT hours you believe you have spent, 4 whether it be case specific or general; is that 5 fair? 6 A. Yes, that's correct. 7 Q. Okay. And the same with respect to 8 Prolift. You have case-specific hours that you've 9 spent for the Prolift? 10 A. Yes. 11 Q. And is that also information that you 12 could provide, if asked to? 13 A. Yes. 14 Q. Are there any other products other than 15 the TVT Retropubic and the Prolift device that you 16 have been asked to offer opinions on related -- and 17 I'm talking about Ethicon products. 18 MS. CRAWFORD: I'm going to object again 19 to the extent it hasn't been designated and it's 20 potentially work product, so I want to tread 21 carefully here. 22 So just answer yes or no. If it's a yes, I 23 might have to ask her a question off the record 24 before she can answer it.</p>	<p style="text-align: right;">Page 41</p> <p>1 2015, at least with respect to TVT, you had not 2 submitted a single invoice related to the work you 3 had completed. Is that still the case? 4 A. Yes. 5 Q. Okay. Have you submitted any invoices 6 related to the Prolift either case specific or 7 general work you've done? 8 A. No. 9 MS. CRAWFORD: Hey, Tom, just for the 10 record, I just want to make sure we're clear. 11 Again, while she did testify in advance of the 12 Corbet case, it was not Corbet. It wasn't 13 captioned Corbet. It was general for the 14 New Jersey TVT Retropubic. 15 MR. CARTMELL: Okay. I appreciate that. 16 Thanks. I've been misstating that. 17 BY MR. CARTMELL: 18 Q. But I'm actually, when I talk about 19 that, talking about your December 2015 deposition; 20 is that okay, doctor? 21 A. Yes, that's correct. 22 Q. You understand that? 23 A. I understand. 24 Q. Okay. So to this day, even though</p>

<p style="text-align: right;">Page 42</p> <p>1 you've been working in this litigation for over 2 three years, you still have never sent an invoice 3 or been paid any amount by Ethicon for the work 4 you've done in the mesh litigation as a whole; is 5 that fair? 6 A. Yes. 7 Q. Okay. Why is it that you haven't 8 submitted any invoices? 9 A. I think it's a combination of two 10 things. Number one, my life is incredibly busy and 11 crazy and I have hardly enough time to do what I 12 need to do normally, so I get behind on paperwork, 13 and number two is that my reason for doing this is 14 not solely as a financial compensation issue that 15 I'm dependent upon that compensation. I do this 16 because I believe strongly in the product, and 17 the -- and I disagree strongly with the allegations 18 of the plaintiffs' experts regarding the problems 19 associated with this. 20 Q. But your intent, I take it, doctor, is 21 to actually submit invoices at some point and be 22 paid, fair enough? 23 A. Most likely, yes, at some point. 24 Q. Okay. Okay. Is there an agreement you</p>	<p style="text-align: right;">Page 44</p> <p>1 debating that ... 2 Q. I don't mean to interrupt you, but I can 3 try to speed this along. You testified in your 4 December 2015 deposition, I believe, that you had 5 not used the TVT Retropubic mesh product for over 6 five years, and I guess my question is: Is that 7 still the case? In other words, you have not used 8 the TVT Retropubic product since December of 2015. 9 A. Yes, that's correct. I only use the TVT 10 Exact. 11 Q. Okay. And that was -- you anticipated 12 my next question, but how long has it been since 13 you used any other midurethral sling other than the 14 TVT Exact? 15 A. I've used both within the last month. 16 I've used Boston Scientific Advantage as well as a 17 TVT Exact within the last month. 18 Q. Okay. I thought you said that you only 19 used the TVT Exact, but is it your testimony that 20 to this day you used both the Boston Scientific 21 Advantage and the TVT Exact? 22 A. Yes. 23 Q. And is there a reason why you might use 24 one or the other? In other words, are there</p>
<p style="text-align: right;">Page 43</p> <p>1 have with Ethicon related to when you'll be paid? 2 A. No. 3 Q. Do you have a written consulting 4 agreement with Ethicon related to this litigation? 5 A. I don't recall. I think I've been sent 6 documents, but I don't think that I've actually 7 signed it and sent it back. 8 Q. Okay. But your memory is that you were 9 sent a contract by Ethicon. 10 A. At some point in the last three years, 11 yes. 12 Q. Okay. And you still have a copy of 13 that, I take it? 14 A. I have no idea. 15 MR. CARTMELL: I'm going to ask for that 16 as well, Kelly, just so you'll know, and, doctor, 17 you can look and just let me know if you have it. 18 BY MR. CARTMELL: 19 Q. Let me move on here. I want to talk now 20 about your use of midurethral slings. Is it fair 21 that you have not used the TVT Retropubic 22 midurethral sling since approximately -- well, tell 23 me when, approximately when. 24 A. That's a good question. We were</p>	<p style="text-align: right;">Page 45</p> <p>1 certain patients you use the Exact in and certain 2 patients that you use the Advantage in? 3 MS. CRAWFORD: I'm just going to object 4 as beyond the scope of this deposition, but I'll 5 allow her to answer the question. 6 THE WITNESS: My decision is not patient 7 specific. My decision is based on other factors. 8 BY MR. CARTMELL: 9 Q. What are those? 10 A. Well, part of it is dependent upon what 11 we have in the room, whether they have pulled the 12 TVT Exact or the Boston Scientific and/or both for 13 being available in the room. Part of it is whether 14 I am at a hospital that doesn't necessarily offer 15 or carry the Boston Scientific sling. One of the 16 hospitals tends to be more Ethicon related. Part 17 of the decision is, when I'm in the process of 18 doing my training for both fellows and residents, 19 to give them the opportunity to use more than one 20 type of sling device so that they can determine 21 which one they may prefer. 22 Q. Okay. Thank you. Now you testified 23 previously that you were implanting 100 plus 24 midurethral slings per year. Is that still the</p>

<p style="text-align: right;">Page 46</p> <p>1 case?</p> <p>2 A. Yes.</p> <p>3 Q. And so, for example, in 2015 your</p> <p>4 testimony is that you personally would have</p> <p>5 implanted 100 plus midurethral slings; is that</p> <p>6 fair?</p> <p>7 A. Yes. 2015 may have been a few less</p> <p>8 because I had surgery myself, and so I was out of</p> <p>9 the office for two months, so ... but typically</p> <p>10 that's the numbers that we have with our practice.</p> <p>11 Q. Okay. And you personally, can you</p> <p>12 ballpark it, of those 100 plus, what percentage of</p> <p>13 those would be the Exact versus a Boston Scientific</p> <p>14 Advantage?</p> <p>15 A. No, I can't.</p> <p>16 Q. Is it about equal?</p> <p>17 A. It's varied a little bit depending upon</p> <p>18 the year. I think now it's probably pretty close</p> <p>19 to equal.</p> <p>20 Q. Okay. You testified in the past that</p> <p>21 you keep records of complications your midurethral</p> <p>22 sling patients have; is that fair?</p> <p>23 A. Yes, I keep a list of patients who have</p> <p>24 had complications with a TVT that I've had to</p>	<p style="text-align: right;">Page 48</p> <p>1 A. I don't know that it would.</p> <p>2 Q. Would the list tell us what the</p> <p>3 complication was?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And are some of those patients'</p> <p>6 complications pain?</p> <p>7 A. No.</p> <p>8 Q. Are they all erosions or some type of</p> <p>9 urinary dysfunction?</p> <p>10 A. One erosion and the remainder were</p> <p>11 voiding issues.</p> <p>12 Q. Okay.</p> <p>13 MR. CARTMELL: Kelly, I'll also submit a</p> <p>14 request for that list. And I understand there are</p> <p>15 HIPAA issues, but I think if we just get it in a</p> <p>16 format that would not violate that.</p> <p>17 MS. CRAWFORD: You send the request, and</p> <p>18 we will respond to it as to whether we can or can't</p> <p>19 produce it.</p> <p>20 MR. CARTMELL: Okay.</p> <p>21 BY MR. CARTMELL:</p> <p>22 Q. Now, I think you testified in your</p> <p>23 December 2015 deposition that four or five of your</p> <p>24 patients who have had midurethral slings have sued</p>
<p style="text-align: right;">Page 47</p> <p>1 perhaps reoperate on.</p> <p>2 Q. And do you have that list currently?</p> <p>3 A. Not with me right now.</p> <p>4 Q. No, I understand, but in your possession</p> <p>5 somewhere.</p> <p>6 A. Yes, I do.</p> <p>7 Q. And how long have you been keeping that</p> <p>8 list? In other words, what year did you start</p> <p>9 doing that?</p> <p>10 A. Probably from fairly, I mean, for over</p> <p>11 the last ten years or so. I mean, it's -- I don't</p> <p>12 remember if I started it the very first year I was</p> <p>13 doing midurethral slings, but most of the time</p> <p>14 period.</p> <p>15 Q. And does that list just include patients</p> <p>16 that you have had to reoperate on?</p> <p>17 A. The list does, yes.</p> <p>18 Q. How many patients are on that list?</p> <p>19 A. I have taken back to the operating room</p> <p>20 approximately 13 or 14 patients of the slings that</p> <p>21 I've done.</p> <p>22 Q. How many of those were Ethicon products?</p> <p>23 A. I can't tell you that.</p> <p>24 Q. The list would tell us that?</p>	<p style="text-align: right;">Page 49</p> <p>1 you; is that correct?</p> <p>2 MS. CRAWFORD: I'm going to object to</p> <p>3 beyond the scope again. If this is something that</p> <p>4 could have or was asked before the December</p> <p>5 deposition, I think it's beyond the scope of this</p> <p>6 deposition.</p> <p>7 THE WITNESS: Do I answer this?</p> <p>8 MS. CRAWFORD: I think it's -- I mean, I</p> <p>9 can't tell her not to, but I think it's beyond the</p> <p>10 scope of this deposition.</p> <p>11 THE WITNESS: No patients have sued me.</p> <p>12 BY MR. CARTMELL:</p> <p>13 Q. Okay. I misunderstood that testimony.</p> <p>14 You did say that you had a list of 15 patients who</p> <p>15 have sued, I guess, in litigation, but maybe that</p> <p>16 means they have sued Ethicon or other physicians;</p> <p>17 is that fair?</p> <p>18 A. I was provided two lists of patients who</p> <p>19 are -- I don't know how they get on the list for</p> <p>20 either New Jersey or maybe West Virginia --</p> <p>21 possible involvement in litigation against Ethicon.</p> <p>22 So I've seen that list of -- from the two different</p> <p>23 states and two different sources, and on that list</p> <p>24 were 15 patients including patients who have not</p>

<p style="text-align: right;">Page 50</p> <p>1 even had midurethral slings done or not even had 2 Prolifts done. 3 Q. Okay. So you were somehow involved in 4 the care and treatment with those patients; is that 5 fair? 6 A. Yes. 7 Q. And has a new list since that time been 8 provided with an increased number of patients? 9 MS. CRAWFORD: You know, Tom, I'm just 10 going to object. I believe what we might be 11 talking about is something that is specific to a 12 New Jersey court order, and I'm not going to stop 13 you from asking the questions, but I'm not sure the 14 doctor is in a position to respond adequately to 15 what you're asking her. 16 BY MR. CARTMELL: 17 Q. I'm just asking if there's been an 18 update to that list of 15 that you've seen, doctor. 19 A. I have not been provided with another 20 list since the December. 21 Q. Do you know whether there are any 22 additional patients than that 15 since that time? 23 A. I don't know. 24 Q. Okay. I'm looking through my notes</p>	<p style="text-align: right;">Page 52</p> <p>1 MS. CRAWFORD: Has she personally done 2 any studies? Is that the question? 3 BY MR. CARTMELL: 4 Q. Any research, yes. 5 A. I've had clinical experience with 6 looking at it and working with it, but I haven't 7 done a scientific protocol research. 8 Q. Is the laser-cut mesh stiffer than the 9 mechanical-cut mesh? 10 A. From a -- from a tactile standpoint, you 11 don't really feel a lot of difference with it. I 12 would sort of -- if you were to give them to me, I 13 wouldn't cause -- I wouldn't determine that 14 stiffness was the difference between the two. 15 Q. Have you ever seen any internal Ethicon 16 studies or documents related to the laser-cut mesh 17 being stiffer than the mechanical-cut mesh? 18 A. I don't recall. 19 Q. Okay. Do you have an opinion regarding 20 whether or not the mesh in the TVT degrades in any 21 amount within a woman's pelvis? 22 A. In my experience and my review of the 23 literature I do not think that degradation is a 24 significant or clinical relevant issue within a</p>
<p style="text-align: right;">Page 51</p> <p>1 here. 2 MR. CARTMELL: Can we take a break for 3 about five minutes and I'll try to sort this out 4 and try to pare it down? 5 MS. CRAWFORD: And we'll both take 6 restroom breaks. 7 MR. CARTMELL: All right. Thank you. 8 (Proceedings recessed at 11:43 a.m.) 9 (In session at 11:49 a.m.) 10 BY MR. CARTMELL: 11 Q. Okay. Doctor, we're back on the record 12 after a short break. Are you ready to proceed? 13 A. I am. 14 Q. My understanding is we have five minutes 15 left. Let me ask you, do you know sitting here 16 today what the pore size of the TVT Retropubic mesh 17 is? 18 A. Yes. 19 Q. What is it? 20 A. 1,079 microns, I believe. 21 Q. Okay. And have you done any research or 22 study to determine how stiff or whether there's a 23 difference in stiffness between the laser-cut mesh 24 and the mechanical-cut mesh?</p>	<p style="text-align: right;">Page 53</p> <p>1 patient. 2 Q. Let me just clarify. It sounds like 3 you're not saying there is not some degree of 4 degradation; you're just saying it's not clinically 5 significant. Is that fair? 6 A. No, I'm saying it's not -- definitely 7 not clinically significant, and trying to determine 8 if something is a nonclinically significant 9 degradation is difficult to do. I think that 10 the -- 11 Q. Okay. 12 A. -- studies -- I'm not done. I think 13 that the studies that have looked at degradation, 14 many of them have not shown degradation to occur in 15 explanted specimens, and the difficulty is, as soon 16 as you explant a specimen, you are creating an 17 artifact in any evaluation of that specimen that 18 can be related to just the process of surgically 19 implanting and/or removing. 20 Q. Okay. Let me back up. I'm not sure I 21 was asking for all that. I just want to know, is 22 your opinion that there is some degree, any degree, 23 whether clinically significant or not, of 24 degradation of the polypropylene mesh inside a</p>

<p style="text-align: right;">Page 54</p> <p>1 woman's vagina -- or do you know?</p> <p>2 A. If you're -- I mean, I can't say that</p> <p>3 there has never been any possible minute amount of</p> <p>4 degradation. I think that that is an impossible</p> <p>5 statement to say one way or the other.</p> <p>6 Q. Okay. So let me ask you this. How many</p> <p>7 mesh implants, whether it be for pelvic organ</p> <p>8 prolapse or for stress urinary incontinence, have</p> <p>9 you removed, either a portion of the mesh or the</p> <p>10 entire mesh?</p> <p>11 A. A lot. Probably --</p> <p>12 Q. How many?</p> <p>13 A. -- somewhere between a hundred and two</p> <p>14 hundred perhaps.</p> <p>15 Q. Okay. Can you ballpark how many of</p> <p>16 those have been stress urinary incontinence</p> <p>17 midurethral slings?</p> <p>18 A. Less than half.</p> <p>19 Q. Okay. And do you refer patients to</p> <p>20 other doctors for them to remove mesh in</p> <p>21 complicated cases?</p> <p>22 A. No.</p> <p>23 Q. You do them yourself?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 56</p> <p>1 you actually had been asked at your prior</p> <p>2 deposition about your use of TVT Retropubic over</p> <p>3 the last years and your use of TVT Exact.</p> <p>4 Do you have an opinion as to whether -- to</p> <p>5 what the difference is in your clinical practice</p> <p>6 between TVT Retropubic and TVT Exact?</p> <p>7 A. Yes.</p> <p>8 MR. CARTMELL: I'm just going -- let me</p> <p>9 just object to the extent I think that exact</p> <p>10 question has been asked in a prior depo, so I do</p> <p>11 think the same thing should apply to you that</p> <p>12 applies to me, but go ahead.</p> <p>13 THE WITNESS: Yes. I think that the</p> <p>14 primary differences between the two are the handle</p> <p>15 that you're using for implanting the device, the</p> <p>16 needle -- the needle size and material, the color</p> <p>17 of the mesh that's being implanted, the sleeve is</p> <p>18 fairly similar, and the handling of the mesh is</p> <p>19 fairly similar.</p> <p>20 MS. CRAWFORD: That's it.</p> <p>21 MR. CARTMELL: Thank you very much,</p> <p>22 everybody.</p> <p>23 MS. CRAWFORD: All right. Tom, first of</p> <p>24 all, I guess this is under the federal rules. She</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. And that hundred to two hundred that you</p> <p>2 have removed polypropylene meshes, has that been --</p> <p>3 well, when has that occurred, over what time</p> <p>4 period?</p> <p>5 A. I mean over, I guess, probably the last</p> <p>6 ten years and stuff, since they have been being</p> <p>7 implanted.</p> <p>8 Q. And you have two partners who also use</p> <p>9 midurethral slings; is that right?</p> <p>10 A. Yes, I do.</p> <p>11 Q. How many have they removed? Do you</p> <p>12 know?</p> <p>13 MS. CRAWFORD: I'm going to object, and I</p> <p>14 also think your time is up, Tom.</p> <p>15 THE WITNESS: No, I don't know. We have</p> <p>16 separate practices.</p> <p>17 MR. CARTMELL: Okay. I think that's all</p> <p>18 the questions I have. Thank you very much.</p> <p>19 MS. CRAWFORD: I just have one follow-up,</p> <p>20 Tom.</p> <p>21 MR. CARTMELL: Okay.</p> <p>22 EXAMINATION</p> <p>23 BY MS. CRAWFORD:</p> <p>24 Q. Doctor, you were asked questions that</p>	<p style="text-align: right;">Page 57</p> <p>1 will read.</p> <p>2 MR. CARTMELL: Okay.</p> <p>3 MS. CRAWFORD: And, number two, the</p> <p>4 exhibits. What do you want to do? There's this</p> <p>5 big binder.</p> <p>6 Doctor, do you care if we send -- do you</p> <p>7 need this stuff back? Shall we make a photocopy?</p> <p>8 THE WITNESS: Yeah, these I'd like</p> <p>9 because these are my originals.</p> <p>10 MS. CRAWFORD: All right. We're going to</p> <p>11 make a photocopy of her originals, which are</p> <p>12 documents -- you don't care about this --</p> <p>13 THE WITNESS: I don't care about that.</p> <p>14 MS. CRAWFORD: -- documents 3 through 8.</p> <p>15 THE WITNESS: 9 -- well, I don't care</p> <p>16 about that one.</p> <p>17 MS. CRAWFORD: And then we'll send those</p> <p>18 with the court reporter and the notebook -- we'll</p> <p>19 send the notebook with the court reporter and the</p> <p>20 original handwritten note with the court reporter.</p> <p>21 Is that okay with you?</p> <p>22 MR. CARTMELL: Yeah, that's fine. I</p> <p>23 would just ask the doctor to maintain the original,</p> <p>24 if she could, and we may ask her to bring those to</p>

Nicolette Horbach, M.D.

<p style="text-align: right;">Page 58</p> <p>1 trial.</p> <p>2 MS. CRAWFORD: That's fine. You're going</p> <p>3 to hold on to these and not lose them.</p> <p>4 She'll take the copies, then. We'll send</p> <p>5 the originals with the transcript.</p> <p>6 MR. CARTMELL: Okay. That sounds great.</p> <p>7 MS. CRAWFORD: All right. Thanks, Tom.</p> <p>8 MR. CARTMELL: Okay. See you-all. Have</p> <p>9 a good day.</p> <p>10 //</p> <p>11 (The deposition of NICOLETTE HORBACH,</p> <p>12 M.D. adjourned at 11:57 a.m.)</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 60</p> <p style="text-align: center;">ERRATA</p> <p>2 NAME OF CASE: In re Ethicon</p> <p>3 DATE OF DEPOSITION: March 25, 2016</p> <p>4 INSERT REASON FOR CHANGE:</p> <p>5 1. To clarify the record.</p> <p>6 2. To conform to the facts.</p> <p>7 3. To correct a transcription error.</p> <p>8 Page _____ Line _____ Reason _____</p> <p>9 From _____ to _____</p> <p>10 Page _____ Line _____ Reason _____</p> <p>11 From _____ to _____</p> <p>12 Page _____ Line _____ Reason _____</p> <p>13 From _____ to _____</p> <p>14 Page _____ Line _____ Reason _____</p> <p>15 From _____ to _____</p> <p>16</p> <p>17</p> <p>18 _____</p> <p>19 NICOLETTE HORBACH, M.D.</p> <p>20</p> <p>21 Subscribed and sworn to before me this _____ day of</p> <p>22 _____, 20 ____.</p> <p>23 _____ (Notary Public)</p> <p>24 My Commission expires: _____</p>
<p style="text-align: right;">Page 59</p> <p style="text-align: center;">ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, NICOLETTE HORBACH, M.D., do hereby</p> <p>4 acknowledge that I have read and examined the</p> <p>5 foregoing testimony and that the same is a true,</p> <p>6 correct and complete transcription of the testimony</p> <p>7 given by me, with the exception of the noted</p> <p>8 corrections, if any, appearing on the attached errata</p> <p>9 page.</p> <p>10 _____</p> <p>11 _____</p> <p>12 DATE NICOLETTE HORBACH, M.D.</p> <p>13</p> <p>14</p> <p>15</p> <p>16 Subscribed and sworn to before me this _____ day of</p> <p>17 _____, 20____.</p> <p>18 _____ (Notary Public)</p> <p>19 My Commission expires: _____</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 61</p> <p style="text-align: center;">C E R T I F I C A T E</p> <p>2</p> <p>3 I, LINDA S. KINKADE, Registered Diplomat</p> <p>4 Reporter, Certified Realtime Reporter, Registered</p> <p>5 Merit Reporter, Certified Shorthand Reporter, and</p> <p>6 Notary Public, do hereby certify that prior to the</p> <p>7 commencement of examination the deponent herein was</p> <p>8 duly sworn by me to testify truthfully under</p> <p>9 penalty of perjury.</p> <p>10 I FURTHER CERTIFY that the foregoing is a</p> <p>11 true and accurate transcript of the proceedings as</p> <p>12 reported by me stenographically to the best of my</p> <p>13 ability.</p> <p>14 I FURTHER CERTIFY that I am neither counsel</p> <p>15 for nor related to nor employed by any of the</p> <p>16 parties to this case and have no interest,</p> <p>17 financial or otherwise, in its outcome.</p> <p>18 IN WITNESS WHEREOF, I have hereunto set my</p> <p>19 hand and affixed my notarial seal this 27th day of</p> <p>20 March 2016.</p> <p>21 My commission expires: July 31, 2017</p> <p>22 _____</p> <p>23 NOTARY PUBLIC IN AND FOR</p> <p>24 THE DISTRICT OF COLUMBIA</p>